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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,622	04/02/2004	Joseph R. Garlich	224297	2375
23460 7590 05/18/2007 LEYDIG VOIT & MAYER, LTD TWO PRUDENTIAL PLAZA, SUITE 4900 180 NORTH STETSON AVENUE CHICAGO, IL 60601-6731			EXAMINER JONES, DAMERON LEVEST	
			ART UNIT 1618	PAPER NUMBER
			MAIL DATE 05/18/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/817,622	<b>Applicant(s)</b> GARLICH ET AL.	
	<b>Examiner</b> D. L. Jones	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,2,6,7,11-14,17-20,23,25,27,29,31,33,35-37 and 76-78 is/are pending in the application.
- 4a) Of the above claim(s) 76 (in part) and 77 (in part) is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,6,7,11-14,17-20,23,25,27,29,31,33,35-37 and 76 (in part), 77 (in part), and 78 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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## **ACKNOWLEDGMENTS**

1. The Examiner acknowledges receipt of the amendment filed 1/26/07 wherein claims 1, 12, 14, 27, 29, 31, 33, 35, and 36 are amended; claims 3-5, 8-10, 15, 16, 21, 22, 24, 26, 28, 30, 32, 34, and 38-74 are canceled; and claims 76-78 are added.

**Note:** Claims 1, 2, 6, 7, 11-14, 17-20, 23, 25, 27, 29, 31, 33, 35-37, and 76-78 are pending.

## **RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS**

2. Applicant's response filed 1/26/07 is acknowledged. The outstanding rejections are WITHDRAWN.

## **NEW GROUNDS OF REJECTION**

### **112 First Paragraph Rejection**

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 2, 6, 7, 11-14, 17-20, 23, 25, 27, 29, 31, 33, 35-37, and 76-78 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation. The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are (1) nature of the invention; (2) state of the prior art; (3) level of one of ordinary skill in the art; (4) level of predictability in the art; (5) amount of direction and guidance provided by the inventor; (6) existence of working examples; (7) breadth of claims; and (8) quantity of experimentation needed to make or use the invention based on the content of the disclosure.

(1) Nature of the invention

The invention is directed to methods of inhibiting cell death by administering a cell protection factor in combination with a bone targeting agent.

(2) State of the prior art

The state of the prior art is that the inhibition of cell death is not an absolute guarantee in mammals wherein cell types and response to various substances and physiological conditions depends on the subject that is administered the substance.

According to Webster's Dictionary (i.e., Webster's II, New Riverside University Dictionary, 1994, page 629), the term 'inhibit' means to restrict; hold back; restrain; or prohibit. Furthermore, it is noted that the term 'prohibit' is equivalent to 'prevent' (see Webster's II, New Riverside University Dictionary, 1994, page 940). As a result, there is no absolute predictability of which cell types would avoid cell death, even in view of the seeming high level of skill in the art. The existence of these obstacles establishes that

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the knowledge in the art would hinder one of ordinary skill in the art from accepting any regimen as being acceptable for inhibiting all types of cell death in mammals.

**Note:** In Applicant's specification (paragraph [0062]), it is disclosed that the cell protection factor mediates at least a 5% reduction or inhibition of cell death (e.g., at least a 10%, 15%, or 20% reduction of inhibition of cell death). Thus, the use of Applicant's term 'inhibit' not only encompasses a reduction in cell death, but complete cell death as well which is equivalent to 'preventing' cell death.

(3) Level of one of ordinary skill in the art

The level of one of ordinary skill in the art is high. There is no evidence of record which would enable the skilled artisan in the identification of all types of cells wherein cell death would be inhibited if a cell protection agent and bone targeting agent are administered to a subject. Applicants have not provided any competent evidence or disclosed tests that are highly predictive for inhibiting cell death in all types of mammalian cells as claimed.

(4) Level of predictability in the art

The art pertaining to the inhibiting cell death is highly unpredictable. Determining the various types or classes of cells wherein cell death is inhibited by administering a cell protection factor in combination with a bone targeting agent requires various experimental procedures and without guidance that is applicable to all mammals, there would be little predictability in performing the claimed invention.

(5) Amount of direction and guidance provided by the inventor

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There is no evidence of record which would enable the skilled artisan in the identification of the mammals whom cell death is prevented by administering a bone targeting agent and a cell protection factor. Applicant's limited guidance does not enable the public to determine which mammalian cell deaths are inhibited based on administering a cell protection agent in combination with a bone targeting agent. There is no directional guidance for the types or classes of mammalian cells wherein cell death is prohibited. The evidence of record does not provide support as to exactly what specific cell types when administered the desired composition avoids cell death. Hence, there is no enablement for inhibiting all possible mammalian cell death.

(6) Breadth of claims

The claims are extremely broad due to the vast number of possible mammalian cells known to exist.

(7) Quantity of experimentation needed to make or use the invention based on the content of the disclosure

The specification does not enable any person skilled in the art to which it pertains to use the invention commensurate in scope with the claims. In particular, the specification fails to enable the skilled artisan to practice the invention without undue experimentation because of the difficulty in determining the specific cell types wherein cell death is inhibited by administering the bone targeting agent and cell protection agent. Furthermore, based on the unpredictable nature of the invention, the state of the prior art, and the extreme breadth of the claims, one skilled in the art could not perform the claimed invention without undue experimentation.

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### **ELECTION BY ORIGINAL PRESENTATION**

5. Newly submitted claims 76 and 77 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons. A restriction requirement was made and Applicant elected to prosecute Group III. The restriction was deemed proper and the search was not expanded beyond the elected group.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 76 (in part) and 77 (in part) are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### **COMMENTS/NOTES**

6. The full scope of the elected Group III was conducted. Group III is directed to a method of inhibiting cell death wherein the cell protection factor is a compound of Formula (IV) (see the restriction requirement mailed 3/17/06). Thus, the claims have not been examined beyond the elected invention.

7. It should be noted that no prior art has been cited against the instant invention. In particular, the claims are distinguished over the prior art of record because the prior art neither anticipates nor renders obvious a method of inhibiting cell death by


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administering a cell protection factor of Formula (IV) in combination with a bone targeting agent.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
D.L. Jones  
Primary Examiner  
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May 10, 2007